

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 20375/S010

APPROVAL LETTER

NDA 20-375/S-010

JUN 11 1998

Berlex Laboratories, Inc.
Attention: Mr. Geoffrey P. Millington
Manager, Drug Regulatory Affairs
340 Changebridge Road
P. O. Box 1000
Montville, NJ 07045-1000

Dear Mr. Millington:

Please refer to your supplemental new drug application dated December 16, 1997, received December 24, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara® (estradiol transdermal system).

The User Fee goal date for this application is June 24, 1998.

The supplemental application provides for the removal of the mixing and coating operations for Climara from

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Diane Moore, Project Manager, at (301) 827-4260.

Sincerely,

JS

6/11/98

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader
Division of New Drug Chemistry II
@ Division of Reproductive and Urologic Drug
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:

Original NDA 20-375
HFD-580/Div. Files
HFD-580/CSO/D.Moore
HFD-580/LRarick/MMann/MRhee/AMitra
HFD-820/DNDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: dm/June 10, 1998/n20375S010AP

Concurrence:

TRumble, AMitra 06.10.98/MRhee, DShames 06.11.98

APPROVAL (AP)

151 4/1/98

ORIGINAL

JUN 10 1998

**DIVISION OF REPRODUCTIVE AND UROLOGIC DRUG
PRODUCTS**

**REVIEW OF CHEMISTRY MANUFACTURING AND CONTROLS
CHEMIST'S REVIEW**

1. NDA NUMBER: 20-375
2. NAME AND ADDRESS OF APPLICANT
Berlex Laboratories, Inc.
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000
3. SUPPLEMENT NUMBER/DATE/DATE ASSIGNED
SCS-010/12-16-97/12-24-97
4. NAME OF THE DRUG: Climara[®] (estradiol transdermal system)
5. NONPROPRIETARY NAME: Estradiol Transdermal System
6. SUPPLEMENT PROVIDES FOR: Removal of the mixing and coating operations for Climara from
7. AMENDMENTS/REPORTS/ DATE: None
8. PHARMACOLOGICAL CATEGORY
Estrogen
9. HOW DISPENSED
Prescription
10. RELATED IND/NDA/DMF/SUPPLEMENT
DMF
11. DOSAGE FORM : Transdermal
12. POTENCY
0.05 , 0.075 and 0.1 mg/day
13. CHEMICAL NAME AND STRUCTURE
 $C_{18}H_{24}O_2 \cdot \frac{1}{2} H_2O$
MW = 281.4

Estra-1,3,5(10)-triene-3,17 β -diol, hemi hydrate